

Response Strategy for a Smallpox Outbreak: Epidemiology and Surveillance Team

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Purpose of this Document

This document complements the [Smallpox Appendix](#), which contains agent-specific information, and the Biological Incident Annex (BIA) [[?-URL](#)], which outlines response activities—including the mission, objectives, and tasks of the Epidemiology and Surveillance Team (EST) in the CDC Emergency Operations

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Center (EOC). [BIA Resource A]

This strategy describes the tools and procedures to facilitate efficient data collection; ensure timely and accurate data transmission; and streamline data management, analysis, and reporting. It will guide the EST—as well as responders in State, Territory, Tribal, and Local jurisdictions (STTLs)—in performing the primary epidemiology and surveillance response activities during a smallpox outbreak: 1) notification and surveillance; 2) data collection and transmission; 3) Data management, statistical analysis, and interpretation; and 4) reporting.

Notification and Surveillance

Definitions. The CDC [Smallpox Appendix](#) defines a case of smallpox and the historical epidemiology of the disease. The [Council for State and Territorial Epidemiologists \(CSTE\)](#) and the World Health Organization (WHO) [International Health Regulations \(IHR 2005\)](#) provide case definitions for purposes of notification.

Smallpox Notification in the US. Within four hours of detecting a probable or confirmed case of smallpox, STTs will verbally notify subject matter experts (SMEs) via the CDC EOC, as recommended by CSTE. After CDC activates the EOC, case notification will go directly to the EST. If verbal notification of individual cases becomes impractical, the EST will recommend that STTs provide a daily summary of new cases.

Notification to International Partners. CDC will immediately notify WHO if a confirmed case of smallpox occurs, as required under [IHR 2005](#). Following initial notification, the EST will continue to comply with relevant international regulations and incorporate WHO guidance in their surveillance and notification procedures.

Active Case Finding. The EST will work with the National Center for Health Statistics to encourage STTs to activate passive surveillance systems (e.g., death registries). It will also establish a liaison with the EOC Team responsible for identifying potential cases entering the US.

Syndromic Surveillance. Smallpox lesions are unique, thus precluding the usefulness of syndromic surveillance for active case finding. However, if the nature of the outbreak impedes timely notification, the EST may recommend that STTLs and the CDC [BioSense](#) program actively review their data for rash-fever syndromes, a proportion of which may indicate probable new cases, or clinical diagnoses of smallpox.

Varicella case notification. The EST will encourage STTs to notify the EOC within 4 hours of detecting a varicella infection resulting in hospitalization or death. Although the Varicella Surveillance Program will triage these cases, the EST may assist with investigation.

Data Collection and Transmission

Throughout the response, the EST will receive case notification and investigation data in the form of individual and summary reports. The level of detail and frequency with which STTs send data to the EST will vary, depending upon each jurisdiction's available resources. (See *Data Transmission*)

Smallpox Outbreak System (SOS). The EST will recommend that STTLs use the Smallpox Outbreak System (SOS), which combines Epi Info™ with a Visual Studio/C# interface, to electronically collect and transmit data. Jurisdictions will be able to download a personal copy of the SOS from a dedicated, encrypted file transfer protocol (FTP) link located on the Smallpox webpage. [Attachment A1] After unzipping the SOS files, users will be able to access the Smallpox Menu to retrieve instructions; data collection forms; scripts for exporting, analyzing, and mapping data; and links to resources and situation reports. [Attachment A2] Because the SOS downloads to the computer desktop, users will be able to control access to, and the security of, their data.

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Hand-Held Devices for Data Collection. Field staff can use SOS forms to collect and transmit data if Epi Info™ is on the device. STTLs can download this application, free of charge, from iTunes (Apple devices) or Google Play (Androids). (**Attachment A3**; see also SOS Resources)

Data Collection Forms. The SOS contains four data collection forms:

- Contact Information and Reporting Jurisdiction (CIRJ) [**Attachment A.4.a.i**]
- Case Investigation Form (CIF) [**Attachment A.4.a.ii-iv**]
- Summary Notification Form (SNF) [**Attachment A.4.v**]
- Summary of Contacts and Exposures Form (SCEF) [**Attachment A.4.vi**]

Questions on the SOS forms have properties and codes that minimize data entry errors. Users can view and change these properties and codes, but will be strongly encouraged to consult with the EST to safeguard data integrity. If the EST makes significant changes to forms or the Epi Info™ application, they will notify jurisdictions to re-load the SOS and will perform data checks and recodes to previously collected data.

OMB approval. If CDC is assisting an STTL under an Epi Aid agreement, OMB will approve data collection for 90 days. (**BIA Resource C: OMB Approval for Data Collected Under an Epi Aid Agreement**) If data collection continues past this time or there is no Epi Aid agreement, the EST will apply for emergency OMB approval to collect data for 6 months. During this time, the EST will ask SMEs in the Pox Rabies Branch (PRB) to apply for renewed approval of questions on the Smallpox Post-Event Surveillance (SPES) Form, which contains the majority of CIF questions. The EST will work with PRB and the National Notifiable Disease Surveillance System (NNDSS) to seek OMB approval for all other questions on the SOS forms.

Contact Information and Reporting Jurisdiction. Following initial notification, the STTL will select the Outbreak Initiation (OI) tab on the Smallpox Menu of the SOS to complete the CIRJ. [**Attachment A.5**] Information provided on this form will populate fields on other forms and in the data transmission scripts, thus minimizing—if not eliminating—double data entry. The STTL will complete and transmit this form at the beginning of the outbreak and will modify and re-transmit the CIRJ only when contact information changes. The STT will have one CIRJ for each of their local jurisdictions; the EST will have one CIRJ for each STT.

Case Notification Data. CSTE recommends that STTs provide an electronic report to NNDSS by the next business day following case detection and notification. However, during the outbreak, CDC will recommend that STTs send notification data to the EST, rather than NNDSS, by completing and submitting the two Core Data pages of the CIF. [**Attachment A.4.a.ii, pages 2-3**]

Case Summary Notification. The EST will recommend that STTLs use the SNF to compile daily summary data on incident cases. When resources are scarce at the STTL level, summary notifications may be the only data transmitted to CDC.

Investigation of Smallpox Cases. The EST will recommend that STTLs use the CIF to collect standardized data on patient identification; vaccination and medical history; characteristics of the current illness; clinical course and outcome; laboratory tests and results; epidemiology and case classification; and environmental and clinical images. Active links to relevant data collection instruments (*e.g.*, worker safety) will be accessible from the CIF and the Smallpox Menu Instructions button. If a jurisdiction is unable to complete the CIF for each case, the EST will recommend that the STTL limit or suspend case investigations and provide only summary data via the SNF.

Contacts and Exposures. Although STTLs are responsible for contact tracing, the EST will encourage completion and transmission of the SCEF to the EST. The EST will share these data with the EOC Medical Care and Countermeasures (MCCM) Team and, if requested, will assist the MCCM Team and STTLs in monitoring indicators of effective contact tracing and other prevention strategies.

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Data Transmission. CSTE recommends that STTs provide electronic notification to the National Notifiable Disease Surveillance System (NNDSS) by the next business day following case detection. However, CDC will recommend that STTs transmit electronic data directly to the EST rather than to NNDSS.

STTLs will be able to save a date-time stamped copy of the database and create a separate de-identified, encrypted, compressed dataset via Transmit to State or Transmit to CDC selections on the Smallpox Menu. **[Attachment A.4.b]** The EST will encourage jurisdictions to update and transmit data daily—as an e-mail attachment—to their contact at the next jurisdiction level (*e.g.*, local to STT; STT to CDC). The type of data collected and transmitted will depend on the STTLs assessment of their response capacity.

Response Capacity	Data
Phase I: have adequate resources	CIF, all pages
Phase II: resources are dwindling	CIF, Core Data for CDC
Phase III: resources are scarce	SNF

Work in Progress:

- *Modify the OI interface format and develop programming codes to automatically populate transport scripts with jurisdiction-specific information (Epi InfoTM Team)*
- *Writing and modifying instructions (EPRB, PRB, Epi InfoTM Team)*
- *Identify STTLs through CDC programs (*e.g.*, CEFO) and STTL organizations (*e.g.*, NACCHO) to assess the usefulness of the SOS for data collection and transmission. (EPRB, PRB).*

Recommended: Create Epi InfoTM forms with OMB-approved questions for NNDSS generic case notification **[Attachment B]**; and identify a process for STTs to transmit these data directly to both NNDSS and the EST to eliminate double data entry by STTs and improve timely data transmission to NNDSS and the EST.

Data Management, Statistical Analysis, and Interpretation

Prior to, and during the response, the EST may request assistance from an ad hoc Outbreak Response Data Management, Statistical Analysis, and Reporting (ORDMSAR) workgroup to identify gaps; develop SAS[®] templates for recoding, data cleaning, and statistical analysis; and perform additional tasks as needed.

Data management. STTs will send their most current data to the EST via e-mail attachment; the EST will replace each existing STT dataset with the most current version. Team members, assigned to specific jurisdictions, will run coding checks and review potentially incorrect data. Once completed, the team member will store the STT database in a designated folder, pending import to the aggregate STTL database maintained by the EST.

Each form in the SOS has pre-programmed code checks to minimize errors at the data collection level. If the coder overrides these checks, additional code checks capture the uncorrected errors in a separate variable. Before closing the data entry process, pre-programmed prompts remind the coder to review the potentially erroneous data. If not corrected at the STTL level, the EST member will review, evaluate, and follow-up to either correct, recode, or allow the potential error. From the Smallpox Menu, users may export the data to an Extensible Markup Language (xml) file to perform additional data management tasks or perform analyses with other software (*e.g.*, SAS).

Near the end of the EOC EST shift, one EST member will save an archived, date-time stamped copy of the current Epi InfoTM database before importing the updated STT databases into the current aggregate dataset. **[Attachment A.4.c]** The Epi InfoTM import command modifies existing records and appends new records, thus eliminating duplication of records. All databases will be stored on the CDC LAN in designated folders with limited access.

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Statistical Analysis. From the SOS Smallpox Menu, STTLs and the EST may select preprogrammed analyses, data mapping, and data exporting and will have access to data dictionaries and the naming convention for variables. [Attachments A.4.d-f]

The EST will run pre-programmed analyses daily; these will also be accessible to STTLs from the Smallpox Menu or from tab selections on the data entry screens. During the outbreak, the EST may provide additional analyses scripts to STTLs with instructions on how to include them in routine Dashboard analyses. Likewise, instructions will be available if STTLs want to perform other analyses and save Dashboard scripts.

In addition to creating the daily Epi curve, the EST will run pre-scripted Dashboard analyses—also available to STTLs—to perform the following analyses by time, place, and demographic characteristics to describe:

- Frequency and distribution of disease
- Infectiousness, pathogenicity, virulence, and transmission modes of the agent
- Clinical presentation, including discrepancies between known and observed disease characteristics
- Forms of disease (*e.g.*, Ordinary, Hemorrhagic)
- Disease classification (*e.g.*, Confirmed)
- Laboratory tests and results
- Vaccination and medical history
- Medical care and treatment
- Case status (*e.g.*, deceased, recovered)

Interpretation. Upon reviewing analytic results, the EST will:

- Determine the probable source of exposure, transmission setting(s), and spread of disease
- Identify risk factors
- Evaluate the effectiveness of prevention and treatment
- Provide estimates of the “Worried well”

The EST may design epidemiologic studies to test hypotheses generated by analytic findings and perform additional analyses as needed or requested by CDC leadership.

Work in progress:

- Continued development of data entry checks to enhance accuracy (EPRB, PRB, Epi InfoTM Team)
- Creating test data to evaluate the scripts for descriptive analyses (EPRB)

Reporting

The EST will share findings in the form of graphs, charts, time-series analyses, maps, bulleted information and other visual and textual displays and will collaborate with the EOC Communication Team and the Situation Awareness Unit in OPHPR/DEO to prepare oral and written reports for leadership as requested. They will share findings with STTLs through daily posts on the SOS Smallpox Menu Situation Awareness link.

Recommended: Draft a daily report template based on those used in recent responses. [Attachment C]

Composition of the EST, Liaisons, and External Personnel Resources

The BIA outlines the basic composition of the EST, including liaisons with other EOC teams. [BIA Resource D] The EST may reach out to other CDC programs for assistance in accomplishing tasks that fall under the purview of these other programs (*e.g.*, NCHS for mortality surveillance) or areas of expertise (*e.g.*, ATSDR for environmental modeling). In addition, the EST may recruit CDC-wide to staff EST activities in the field.